

## **REMARKS**

### **I. Claim Status**

Reconsideration of the present application is respectfully requested. Claims 1-5, 7-10, 12, 16, 19, 20, 22, 33 and 35 are pending. Claims 6, 11, 13, 14, 15, 17, 18, 21, 23-32 and 34 have been previously canceled without prejudice. No new matter is added by way of this response.

### **II. Summary of Examiner Interview**

Applicants thank the Examiner and his supervisor for their time in participating in the July 22, 2010 interview with the undersigned, and for their careful consideration of this application in general. During the interview, the pending claims were discussed in view of the rejections of record. In particular, the disclosures of U.S. Patent No. 3,257,276 to Broh-Kahn et al. and U.S. Patent No. 5,736,574 to Burnier et al. were discussed. It was argued by the undersigned that in view of Burnier, which describes antimicrobial formulations to be used as an alternative to known antimicrobial agents, and in the absence alcohol (*See*, Burnier at Col. 1, lines 14-33), an artisan of ordinary skill would not be motivated to combine the ingredients of Burnier with those of Broh-Kahn. The Examiner acknowledged Applicant's arguments and requested that they be included in a response to the May 13, 2010 Office Action for consideration.

### **III. Rejections Under 35 U.S.C. § 103(a)**

A. U.S. Patent No. 3,257,276 to Broh-Kahn et al. in view of U.S. Patent No. 5,736,574 to Burnier et al. as evidenced by U.S. Patent No. 4,870,108 to Page

Claims 1, 16, 19 and 22 stand finally rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 3,257,276 to Broh-Kahn et al. (hereafter, "Broh-Kahn") in view of U.S. Patent No. 5,736,574 to Burnier et al. (hereafter, "Burnier") as evidenced by U.S. Patent No. 4,870,108 to Page (hereafter, "Page"). The Examiner maintains that Broh-Kahn describes an oral analgesic hydroalcoholic gel comprising benzalkonium chloride, a gelling agent, alcohol, and water among other ingredients. The Examiner further maintains that Burnier discloses antimicrobial mixtures

comprising an antimicrobial agent and a synergistically effective amount of octoxyglycerin for formulating cosmetic and pharmacological compositions. According to the Examiner, it would have been obvious for an artisan of ordinary skill to combine Burnier's octoxyglycerin with the composition described by Broh-Kahn, which allegedly describes the claimed invention.

Applicants respectfully disagree. To support an assertion of obviousness, the Examiner must show that "all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." M.P.E.P. § 2143. *See also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727 (2007).

Applicants respectfully submit that claims are not obvious over the combined teaching of the cited references because an artisan of ordinary skill would have no reasonable expectation that the compositions of Burnier and Broh-Kahn could be successfully combined into a single composition, as encompassed by the claims.

Broh-Kahn is directed to oral analgesic preparations for treating pain in the oral or buccal cavity. The formulations include a salicylate compound to treat the pain in the form of a hydroalcoholic gel. In addition to salicylic acid, the composition of Broh-Kahn is formulated with benzalkonium chloride and alcohol. *See, e.g.*, Broh-Kahn at Col. 3, lines 57-58; and Col. 5, lines 5-8. In particular, preferred effective formulations of the disclosed composition include alcohol at a concentration of almost 40%:

A preferred effective formulation of the choline salicylate gel preparation is as follows:

|  | Grams |
|--|-------|
| Choline salicylate -----                   | 8.72  |
| Cetyldimethylbenzylammonium chloride ----- | 0.01  |
| Methylcellulose-4,000 -----                | 2.75  |
| Glycerine -----                            | 5     |
| Ethyl alcohol -----                        | 39.16 |
| Oil of anise -----                         | 0.143 |
| Menthol -----                              | 0.057 |
| Cyclohexylsulfamic acid -----              | 0.2   |
| Water—q.s.d. -----                         | 100   |

*See*, Broh-Khan at Col. 5, lines 13-25. In contrast to Broh-Khan, Burnier describes antimicrobial formulations to be used as an alternative to known antimicrobial agents, such that an antimicrobial effect can be achieved while avoiding unpleasant side effects of prior art

antimicrobials, for example, irritation and allergic reactions. Applicants note that the antimicrobial hydroalcoholic gels of Broh-Kahn are prior art to Burnier, as Broh-Kahn issued as a patent almost 29 years prior to the earliest priority date of Burnier. As described by the instant application, antimicrobial alcoholic gels can be irritating, and may cause dermatitis. *See*, pages 13-14, paragraph [0105] of the published application. In addition to disclosing compositions that can be used in place of prior art antimicrobial compositions, Burnier's compositions are also formulated to be used as an alternative to alcohol based formulations, which, like prior art antimicrobials, can cause irritation and allergies. In particular, Burnier discloses the following:

It is common to introduce into cosmetic or dermatological compositions chemical preservatives intended to combat the growth of microorganisms therein . . . These preservatives present the drawback of causing intolerance, such as irritations and/or allergies . . . This is likewise the case for alcohols or polyols, such as ethanol or propylene glycol . . . Thus, need continues to exist for antimicrobial agents having an activity which is at least as effective as the compounds of the prior art, but which do not present the drawbacks associated therewith.

*See*, Burnier at Col. 1, lines 14-33. Thus, in view of Burnier, a skilled artisan would seek to combine octoxyglycerin with antimicrobial agents other than those known in the prior art, for example, as disclosed by Broh-Kahn, in an attempt to avoid unwanted side effects. Furthermore, such compositions would be formulated in the absence of high concentrations of alcohol, for example, as included in the compositions described by Broh-Kahn.

Additionally, in view of Broh-Kahn and Burnier, the skilled artisan would have no reasonable expectation of success in practicing the claimed invention because Burnier does not suggest or describe that octoxyglycerin can be combined with any antimicrobial agents (*e.g.*, benzalkonium chloride as described in Broh-Kahn) other than hydrolipids and lipids.

. . . combinatory immixture of at least one compound exhibiting antimicrobial activity, *selected from among the hydrolipids or lipids*, and at least one glyceryl monoalkyl ether . . . The antimicrobial action of this combination is advantageous since it is milder, while at the same time being at least as effective as that of the compounds of the prior art . . .

*See*, Burnier at Col. 1, lines 41-50 (emphasis added). Indeed, Burnier combines octoxyglycerin with hydrolipids or lipids for the purpose of achieving antimicrobial compounds that can be used

in lieu of the antimicrobial compounds of the prior art to achieve an antimicrobial effect without causing the unwanted side effects of the prior art antimicrobials. As such, an artisan of ordinary skill, with knowledge of Burnier, would be motivated to avoid combining octoxyglycerin with prior art antimicrobials, such as a quaternary ammonium compound, in formulating a cosmetic or dermatological composition.

Applicants further submit that Broh-Kahn discloses gel compositions for use in the oral or buccal cavity, whereby the composition is absorbed through the oral mucosa to provide a local analgesic effect. *See, e.g.*, Broh-Kahn at Col. 1, lines 10-27. In contrast, Burnier is directed to topical antimicrobial cosmetic compositions. In view of the cited references, an artisan of ordinary skill would have no reasonable expectation that the ingredients of Burnier's topical compositions would be compatible with the ingredients of Broh-Kahn's oral compositions. Indeed, such incompatibility is recognized by U.S. Patent No. 4,393,076 to Noda et al. (hereafter, "Noda"), which was cited by the Examiner in rejecting the claims under 35 U.S.C. 103(a), discussed below. In particular, Noda discloses the following:

It is seen from the foregoing that, in general, *medicinal ingredients which are effective when orally administered are not necessarily effective when used as a gel composition for external application* to integument and, therefore, they must be intensively studied to find their uses...

*See*, Noda at Col. 2, lines 52-57 (emphasis added). Thus, in view of Noda, the skilled artisan would have an understanding that the ingredients of Broh-Khan and those of Burnier would be incompatible since Burnier's composition is for external administration, and Broh-Kahn's composition is for absorption through the oral mucosa.

Applicants also submit that the non-obviousness of the claims is further supported by the surprising and unexpected antimicrobial synergy achieved by combining octoxyglycerin and a quaternary ammonium compound (*e.g.*, benzalkonium chloride). For example, as disclosed in Example 4 of the specification (*see*, the specification at pages 38-42), octoxyglycerin produced a 33 fold reduction in microbial growth compared to control, and benzalkonium chloride produced a 6.25 fold reduction in microbial growth compared to control. However, when the two agents were combined together in a single composition, microbial growth was reduced by 12,500 fold compared to control. Such an effect is extraordinarily synergistic over the expected additive effect of the two agents (*i.e.*, 39.25 fold reduction). *See*, the specification at page 40, Table 5.

An artisan of ordinary skill, in view of the cited references, would have no way of predicting that octoxyglycerin and a quaternary ammonium compound would interact synergistically. Further, as discussed above, the skilled artisan would not only be unable to predict that the two agents could interact synergistically, but in view of the references, the skilled artisan would have no reasonable expectation that the two agents could even be combined together to have any effect. Specifically, without knowledge of the instant application, in which Applicants demonstrate that octoxyglycerin and a quaternary ammonium compound interact synergistically, the skilled artisan would not have expected or predicted that the two compounds could be combined to achieve such an effect.

For the foregoing reasons, Applicants submit that the claims are not obvious over the combined teaching of the cited references, and respectfully request that the rejection be withdrawn.

B. Broh-Kahn in view of Burnier and Noda as evidenced by Page

Claim 7 stands rejected under 35 U.S.C. § 103(a) as obvious over Broh-Kahn in view of Burnier and further in view of Noda as evidenced by Page. The Examiner contends that Broh-Kahn describes a hydroalcoholic gel composition comprising benzalkonium chloride, a gelling agent, alcohol, and other ingredients, while Burnier discloses antimicrobial mixtures comprising an antimicrobial agent and synergistic amounts of octoxyglycerin, as previously discussed. The Examiner further alleges that Noda describes an anti-inflammatory and analgesic gel composition comprising methylcellulose or hydroxyethylcellulose. According to the Examiner, it would have been obvious to use Noda's methylcellulose or hydroxyethylcellulose in the composition described by Broh-Kahn and Burnier to produce the claimed invention.

Applicants respectfully disagree and submit that an artisan of ordinary skill would have no expectation that the methylcellulose or hydroxyethylcellulose of Noda could be successfully combined with the composition of Broh-Kahn, as contended by the Examiner. As previously discussed, Broh-Kahn discloses gel compositions for use in the oral or buccal cavity, whereby the composition is absorbed through the oral mucosa to provide a local analgesic effect. *See, e.g.,* Broh-Kahn at Col. 1, lines 10-27. In contrast, Noda is directed to gel compositions for external topical administration. *See, e.g.,* Noda at Col. 2, lines 40-51. Neither Broh-Kahn nor Noda provide the artisan with any guidance or suggestion that the ingredients for a topical

composition as described by Noda could be combined with the ingredients of Broh-Kahn's oral composition to form an effective antimicrobial composition as encompassed by the claims. In particular, as previously discussed, Noda recognizes that in general, ingredients from oral and topical formulations are not usually compatible. *See*, Noda at Col. 2, lines 52-57. Thus, in view of Noda, the skilled artisan would have an understanding that the ingredients of Noda and those of Broh-Kahn would be incompatible since Noda's composition is for external administration, and Broh-Kahn's composition is for absorption through the oral mucosa.

Additionally, as described previously, Burnier provides an artisan of ordinary skill with guidance to combine octoxyglycerin with antimicrobials other than those described by Broh-Kahn, and further, that the octoxyglycerin should be formulated in the absence of Broh-Kahn's high concentrations of alcohol. Combining the methylcellulose or hydroxyethylcellulose with the compositions of Burnier or Broh-Kahn, as described by the Examiner, does not rescue Burnier and Broh-Kahn's failure in describing the claimed invention. For the foregoing reasons, Applicants submit that the claims are not obvious over the cited references and respectfully request that the rejection be withdrawn.

C. Broh-Kahn in view of Burnier and U.S. Patent No. 5,965,610 to Modak et al. as evidenced by Page

Claims 2-5, 8, 9, 10 and 33 stand rejected under 35 U.S.C. § 103(a) as obvious over Broh-Kahn in view of Burnier and further in view of U.S. Patent No. 5,965,610 to Modak et al. (hereafter, "Modak") as evidenced by Page. The Examiner contends that the combined disclosure of Broh-Kahn and Burnier describes a composition comprising benzalkonium chloride, a gelling agent, alcohol and octoxyglycerin. The Examiner further alleges that Modak describes a gel comprising emulsifiers, thickening agents, silicone polymers and other ingredients. According to the Examiner, it would have been obvious to combine Modak's emulsifiers, thickening agents and silicone polymers with the composition defined by the combined disclosure of Broh-Kahn and Burnier to create the claimed invention.

Applicants respectfully disagree. As previously discussed, an artisan of ordinary skill, in view of Broh-Kahn and Burnier, would have no reasonable expectation that the ingredients of Broh-Kahn and Burnier could be successfully combined into a single composition, as encompassed by the claims. Applicants submit that Modak describes emulsifiers, thickening

agents and silicone polymers that can be included in a gel composition. Modak does not cure the deficiencies of Broh-Kahn and Burnier in describing the claimed invention, and as such, combining the disclosure of Modak with those of Broh-Kahn and Burnier does not render the claims obvious. In view of the foregoing, Applicants submit that the claims are not obvious over the cited references and respectfully request that the rejection be withdrawn.

D. Broh-Kahn in view of Burnier and U.S. Patent No. 6,485,716 to Fei et al. as evidenced by Page

Claims 35 stands rejected under 35 U.S.C. § 103(a) as obvious over Broh-Kahn in view of Burnier and further in view of U.S. Patent No. 6,485,716 to Fei et al. (hereafter, "Fei") as evidenced by Page. The Examiner contends that the combined disclosure of Broh-Kahn and Burnier describes a composition comprising benzalkonium chloride, a gelling agent, alcohol and octoxyglycerin. The Examiner further alleges that Fei discloses gel compositions comprising the emollient PPG-3 myristyl ether. According to the Examiner, it would have been obvious to combine Fei's PPG-3 myristyl ether with the composition defined by the combined disclosure of Broh-Kahn and Burnier to create the claimed invention.

Applicants respectfully disagree. As previously discussed, an artisan of ordinary skill, in view of Broh-Kahn and Burnier, would have no reasonable expectation that the ingredients of Broh-Kahn and Burnier could be successfully combined into a single composition, as encompassed by the claims. Applicants submit that Fei provides an emollient that can be included in a deodorant or antiperspirant gel composition. Fei does not cure the deficiencies of Broh-Kahn and Burnier in describing the claimed invention, and as such, combining the disclosure of Fei with those of Broh-Kahn and Burnier does not render the claims obvious. In view of the foregoing, Applicants submit that the claims are not obvious over the cited references and respectfully request that the rejection be withdrawn.

**IV. The Double Patenting rejection**

Claims 1, 2, 3, 5, 7-10, 12, 13, 16, 19, 20, and 22 stand provisionally rejected for nonstatutory obviousness-type double patenting over claims 1, 3-11, and 17 of co-pending application serial no. 10/622,272 (hereafter "the '272 application"). According to the Examiner,

it would have been obvious to combine the ingredients noted in the '272 application to arrive at the presently claimed invention.

Since the rejection is provisional because the allegedly overlapping claims have not yet been patented, to the extent that claim scope overlaps in any patented case, Applicants respectfully submit that the appropriate action will be taken as the Examiner indicates allowable subject matter with regard to the pending rejections under 35 U.S.C. § 103(a).

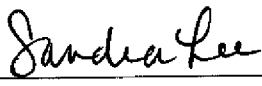


V. **Conclusion**

In view of the above remarks, it is respectfully requested that the application be allowed and passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe that no fee in addition to the fee associated with the Request for Continued Examination is due at this time. However, if any other fee is required, the Commissioner is authorized to charge such fee to Deposit Account No. 02-4377.

Respectfully submitted,  
BAKER BOTTS L.L.P.

Dated: 8/5/2010

  
Sandra S. Lee  
Patent Registration No.: 51,932  
*Attorney For Applicants*

Lisa B. Kole  
Patent Registration No.: 35,225  
*Attorney For Applicants*

30 Rockefeller Plaza  
New York, NY 10112-4498  
(212) 408-2569  
(212) 259-2569 (fax)